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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,269	01/26/2006	James M Chen	263.PF2US	2128
Gilead Sciences 333 Lakeside Drive			EXAMINER	
			O DELL	DAVID K
Foster City, CA 94404			ART UNIT	PAPER NUMBER
			1609	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		01/31/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)				
	10/529,269	CHEN ET AL.				
Office Action Summary	Examiner	Art Unit				
	David K. O'Dell	1609				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on 25 M.	arch 2005	4				
	<u> </u>					
,	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims		·				
4)⊠ Claim(s) <u>1-79</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
·- · · · · · ·	8)⊠ Claim(s) 1-79 are subject to restriction and/or election requirement.					
b) Saim (3) 1-75 are subject to restriction and/or election requirement.						
Application Papers		·				
9) The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of: <ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4)  Interview Summary Paper No(s)/Mail D 5)  Notice of Informal F 6)  Other:	ate				

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## **DETAILED ACTION**

- 1. Claims 1-79 are pending the current application.
- 2. This application is a National Stage Application of International Application No.:

PCT / US03 / 32666 filed October 16, 2003, which claims priority under Title 35, United

States Code § 119(e) of the United States provisional application(s) listed below:

60/418,963 filed October 16, 2002

60/478,783 filed June 16, 2003

## Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claims 9, 13-45, 47-49, 54-67, drawn to compounds bearing a quinoline core, where applicant's Markush structure and individual compounds have Q is  $CR_4$ ,  $A_2$  is  $C(R_2)=(CR_3)$ ,  $A_1$  is  $C(R_2)_2$ , X=O,  $R_2-R_4=H$ , L is  $CH_2$ , Ar is phenyl, and Y=Z is  $C=C-R_1$ , with the proviso that no compound(s) contain(s) phosphorous atom(s).

Group II, claims 9, 13-45, 47-49, 54-67, drawn to compounds bearing a quinoline core, where applicant's Markush structure and individual compounds have Q is  $CR_4$ ,  $A_2$  is  $C(R_2)=(CR_3)$ ,  $A_1$  is C=O, X=O,  $R_2-R_4=H$ , L is  $CH_2$ , Ar is phenyl and Y=Z is  $C=C-R_1$ , with the proviso that no compound(s) contain(s) phosphorous atom(s).

Group III, claims 12-15, 20, 26-44, 47,49, 54-67, drawn to compounds bearing a benzimidazole core and where applicant's Markush structure and individual compounds have Q is  $CR_4$  (where  $R_4$  is H),  $A_2$  is NR (where R is benzyl),  $A_1$  is  $C(R_2)_2$ , X = O, and Y=Z is  $C=C-R_1$ , with the proviso that no compound(s) contain(s) phosphorous atom(s).

Group IV, claims 12-15, 20, 26-44, 47,49, 54-67, drawn to compounds bearing a benzimidazole core and where applicant's Markush structure and individual compounds have Q is  $CR_4$  (where  $R_4$  is H),  $A_2$  is NR (where R is benzyl),  $A_1$  is C=0, X=0, L is  $CH_2$ , Ar is phenyl ,and Y=Z is  $C=C-R_1$ , with the proviso that no compound(s) contain(s) phosphorous atom(s).

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Group V, claims 12-15, 20, 26-44, 47, 49, 54-67, drawn to compounds bearing a benzotriazole core and where applicant's Markush structure and individual compounds have Q is N,  $A_2$  is NR (where R is benzyl), X =0,  $A_1$  is  $C(R_2)_2$  (where  $R_2$  is H), L is  $CH_2$ , Ar is phenyl and Y=Z is C=C-R<sub>1</sub>, with the proviso that no compound(s) contain(s) phosphorous atom(s).

Group VI, claims 12-15, 20, 26-44, 47, 49, 54-67, drawn to compounds bearing a benzotriazole core and where applicant's Markush structure and individual compounds have Q is N,  $A_2$  is NR (where R is benzyl), X is  $C(R_2)_2$ ,  $A_1$  is C=O, L is  $CH_2$ , Ar is phenyl and Y=Z is C=C- $R_1$ , with the proviso that no compound(s) contain(s) phosphorous atom(s).

Group VII, claims 12-15, 20, 26-44, 47, 49, 54-67, drawn to compounds bearing a quinoxaline core and where applicant's Markush structure and individual compounds have Q is  $CR_4$  (where  $R_4$  is H),  $A_2$  is  $N=C(R_3)$  (where  $R_3$  is H), X=O,  $A_1$  is  $C(R_2)_2$  (where  $R_2$  is H) L is  $CH_2$ , Ar is phenyl and Y=Z is  $C=C-R_1$ , with the proviso that no compound(s) contain(s) phosphorous atom(s).

Group VIII, claims 12-15, 20, 26-44, 47, 49, 54-67, drawn to compounds bearing a quinoxaline core and where applicant's Markush structure and individual compounds have Q is  $CR_4$  (where  $R_4$  is H),  $A_2$  is  $N=C(R_3)$  (where  $R_3$  is H), X=O,  $A_1$  is C=O, L is  $CH_2$ , Ar is phenyl and Y=Z is  $C=C-R_1$ , with the proviso that  $R_1$  contains no phosphorous atoms.

Group IX, claims 13-15, 20, 28-44, 46, 49, 54-67, drawn to compounds bearing a pyrido-pyridine core and where applicant's Markush structure and individual compounds have Q is  $CR_4$ ,  $A_2$  is  $C(R_2)=C(R_3)$  (where  $R_2-R_3$  is H),  $A_1$  is C=O, X=O and Y=Z is N-C=X, with the proviso that no compound(s) contain(s) phosphorous atom(s).

Group X, claims 13-15, 20, 28-44, 46, 49, 54-67, drawn to compounds bearing a pyridopyridine core and where applicant's Markush structure and individual compounds have Q is  $CR_4$ ,  $A_2$  is  $C(R_2)=C(R_3)$  (where  $R_2-R_3$  is H), X =O,  $A_1$  is  $CR_2$  (where  $R_2$  is H), and Y=Z is N-C=X, with the proviso that no compound(s) contain(s) phosphorous atom(s).

Group XI, claims 12-15, 20, 26-44, 47, 49, 54-67, drawn to compounds bearing a triazolo-pyridazine core and others not delineated here, with the proviso that no compound(s) contain(s) phosphorous atom(s).

Group XII, claims 9, 13-45, 47-49, 54-67, drawn to compounds of Group I where R<sub>1</sub> contains phosphorous atom(s).

Group XIII, claims 9, 13-45, 47-49, 54-67, drawn to compounds of Group II where R<sub>1</sub> contains phosphorous atom(s).

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Group XIV, claims 12-15, 20, 26-44, 47,49, 54-67, drawn to compounds of Group III where R<sub>1</sub> contains phosphorous atom(s).

Group XV, claims 12-15, 20, 26-44, 47,49, 54-67, drawn to compounds of Group IV where R<sub>1</sub> contains phosphorous atom(s).

Group XVI, claims 12-15, 20, 26-44, 47, 49, 54-67, drawn to compounds of Group V where R<sub>1</sub> contains phosphorous atom(s).

Group XVII, claims 12-15, 20, 26-44, 47, 49, 54-67, drawn to compounds of Group VI where R<sub>1</sub> contains phosphorous atom(s).

Group XVIII, claims 12-15, 20, 26-44, 47, 49, 54-67, drawn to compounds of Group VII where  $R_1$  contains phosphorous atom(s).

Group XIX, claims 12-15, 20, 26-44, 47, 49, 54-67, drawn to compounds of Group VIII where R<sub>1</sub> contains phosphorous atom(s).

Group XX, claims 13-15, 20, 28-44, 46, 49, 54-67, drawn to compounds of Group IX where  $R_1$  contains phosphorous atom(s).

Group XXI, claims 13-15, 20, 28-44, 46, 49, 54-67, drawn to compounds of Group X where  $R_1$  contains phosphorous atom(s).

Group XXII, claims 12-15, 20, 26-44, 47, 49, 54-67, drawn to compounds of Group XI where R<sub>1</sub> contains phosphorous atom(s).

Group XXIII claims 50-51, 53, 68, drawn to methods of preparing compounds of Group I.

Group XXIV claims 50-51, 53, 68, drawn to methods of preparing compounds of Group II.

Group XXV claims 50, 68, drawn to methods of preparing compounds of Group III.

Group XXVI claims 50, 68, drawn to methods of preparing compounds of Group IV.

Group XXVII claims 50, 52, 68, drawn to methods of preparing compounds of Group V.

Group XXVIII claims 50, 52, 68, drawn to methods of preparing compounds of Group VI.

Group XXIX claims 50, 68, drawn to methods of preparing compounds of Group VII.

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Group XXX claims 50, 68, drawn to methods of preparing compounds of Group VIII.

Group XXXI claims 50, 68, drawn to methods of preparing compounds of Group IX.

Group XXXII claims 50, 68, drawn to methods of preparing compounds of Group X.

Group XXXIII claims 50, 68, drawn to methods of preparing compounds of Group XI.

Groups XXXIV to XLIV claims 73-75, 78, drawn to methods of preparing compounds limited to the scope of one of groups XII-XXII.

Groups XLV to LXVI claims 69-72, 76-77, 79 drawn to methods of treatment etc. limited to the scope of one of groups I-XXII.

In order to clarify groups I-XI applicant is provided with Figure 1, which clearly shows the core of each group.

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1. The inventions listed as Groups I-XLVI do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- (f) "Markush practice" The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.
- (i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:
  - (A) All alternatives have a common property or activity; and
  - (B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
  - (B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The

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different variables A<sup>1</sup>, Y, Z, A<sup>2</sup>, Q, R<sup>x2</sup>, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, L etc. result in so many permutations giving both heterocyclic and non-hetero rings, different bonds between atoms, resulting in compounds that have achieved a different status in the art, and thus are drawn to an improper Markush group on the grounds of lack of a common nucleus. Thus lack of unity is apparent.

A preliminary search of a selected core gave numerous iterations, see below:-

G1 C,N G2 Cb,Cy,Hy

Structure attributes must be viewed using STN Express query

=> s 17

SAMPLE SEARCH INITIATED 13:08:05 FILE 'REGISTRY'
SAMPLE SCREEN SEARCH COMPLETED - 5994 TO ITERATE

33.4% PROCESSED 2000 ITERATIONS INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)

SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS: ONLINE \*\*COMPLETE\*\*

BATCH \*\*COMPLETE\*\*

PROJECTED ITERATIONS: 115238 TO 124522 PROJECTED ANSWERS: 979 TO 2017 Art Unit: 1609

Thus it is clear that applicant's compound core is not applicant's contribution over the prior art and the commonly shared structure does not constitute a structurally distinctive portion in view of the existing prior art. Thus there is a lack of unity.

A prior art reference anticipating the claims with respect to one group would not render obvious the same claims with respect to another group. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

2. Applicant is advised that the reply to this requirement to be complete must include the invention to be examined and an election of a species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-21 are generic. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. .An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must

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indicate which are readable upon the elected species. MPEP § 809.02(a). The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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- 3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell whose telephone number is (571) 272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Cecilia Tsang or Andrew Wang can be reached at (571)-272-0562 or (571)-272-0811, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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